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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO.       |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/521,875  | 05/08/2006  | David Foster         | DHN/360/PC/US                | 3290                   |
| 2543  | 7590        | 09/23/2009           |                              |                        |
| ALIX YALE & RISTAS LLP<br>750 MAIN STREET<br>SUITE 1400<br>HARTFORD, CT 06103 |             |                      | EXAMINER<br>SORKIN, DAVID L. |                        |
|   |             |                      | ART UNIT<br>1797             | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>09/23/2009      | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/521,875

**Applicant(s)**

FOSTER, DAVID

**Examiner**

DAVID L. SORKIN

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Because claim 11, requires an o-ring, and claims 13 and 23 depend from claim 11, the phrase "a light seal or O-ring" recited in claims 13 and 23 makes unclear whether an o-ring is required. The fourth paragraph of section 112 requires that dependent claims have all the limitations of their parent claim.
3. Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 15, there is lack of antecedent basis for "the syringe".

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 9, 14-18, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Earle (US 5,975,751). Regarding claim 1, Earle discloses an orthopedic

cement mixing apparatus comprising a mixing chamber (414) and a cylindrical dispensing chamber (421), the mixing chamber having an outlet opening and the dispensing chamber having an inlet opening, the outlet opening and the inlet opening being arranged so as to allow cement mixed in the mixing chamber to pass into the dispensing chamber; closure means (431) having a first position separating the outlet opening of the mixing chamber and the inlet opening of the dispensing chamber; and means (443) for applying a vacuum to the mixing chamber and to the dispensing chamber; characterized in that the apparatus further comprises switching means (444, 446) for switching the applied vacuum between the mixing chamber and the dispensing chamber. Regarding claim 2, the closure means is a piston which, in a first position, is located at the top of the dispensing chamber (see Figs. 12 and 15-18). Regarding claim 3, the dispensing chamber is a cylindrical body of a dispensing syringe (see col. 3, lines 1-5). Regarding claim 9, Earle discloses an orthopedic cement mixing apparatus comprising a mixing chamber (414) and a dispensing chamber (421), the mixing chamber having an outlet aperture and the dispensing chamber having an inlet aperture, the outlet aperture and the inlet aperture being in cement flow communication; and closure means (154/158/431) which, in a first position, separates the outlet aperture from the inlet aperture preventing flow of cement from the mixing chamber to the dispensing chamber; characterized in that the closure means is held in its first position by a releasable fastening means (see col. 12, lines 39-67). Regarding claim 14, Earle discloses an orthopedic cement mixing apparatus comprising a mixing chamber (414) and a dispensing chamber (421), the mixing chamber having an outlet aperture and the

dispensing chamber having an inlet aperture, the outlet aperture and the inlet aperture being in cement flow communication; and closure means (154/158/431) for separating the inlet aperture and the outlet aperture to prevent flow of cement from the mixing chamber to the dispensing chamber, wherein the closure mean is movable between a closed position whereby flow of cement from the mixing chamber to the dispensing chamber is prevented and an open position whereby cement can flow from the mixing chamber to the dispensing chamber. Regarding claim 15, the closure comprising a trap door arrangement whereby cement is mixed in the mixing chamber which is closed, at the bottom, by a slidable closure (153). Regarding claim 16, said trap door arrangement comprises a pullout trap door, wherein the closure comprises a plate (153) slidably located between the mixing chamber and the dispensing chamber, the plate having a closed portion which in its closed position (Fig. 15) prevents the flow of cement from the mixing chamber to the dispensing chamber, and an aperture portion (155), which aligns with the outlet aperture and the inlet aperture to allow cement flow therethrough, the plate being slidably located such that the user can pull the plate to a first position (Fig. 15) whereby the closed portion is located between the inlet aperture and the outlet aperture, and a second position (Fig. 16) wherein the aperture is located between the inlet aperture and the outlet aperture. Regarding claim 17, the plate is provided with a handle (see Figs. 15 and 16). Regarding claim 18, the closure comprises a tap (153) defining a channel or passage (155) therethrough, which fits between the mixing chamber and the dispensing chamber. Regarding claim 20, the apparatus of Earle is capable of being used in the manner discussed in the claim.

Regarding claim 21, the dispensing chamber is a cylindrical body of a dispensing syringe (see col. 3, lines 1-5).

6. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Foster (WO 01/56514). Regarding claim 1, Foster discloses an orthopedic cement mixing apparatus comprising a mixing chamber (1) and a dispensing chamber (2), the mixing chamber having an outlet aperture and the dispensing chamber having an inlet aperture, the outlet aperture and the inlet aperture being in cement flow communication, the apparatus further comprising a mixing paddle (3) extending into said mixing chamber and a rotatable handle (5) coupled to said paddle by a gear mechanism (8,10) arranged such that rotation of said handle causes said paddle to rotate about its own axis and also moves the axis of rotation of the paddle within the chamber whereby the paddle is moved around substantially the entire cement containing region of the interior of the chamber. Regarding claim 5, the mixing chamber is a bowl (1).

7. Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter (US 370,335). Regarding claim 7, Hunter discloses an apparatus comprising a mixing chamber (A), a mixing paddle (I) extending into said chamber and a rotatable handle (G) coupled to said paddle by a gear mechanism (E,J) arranged such that rotation of said handle causes said paddle to rotate about its own axis and also move the axis of rotation of the paddle within the chamber whereby the paddle is moved around substantially the entire region of the interior of the chamber; characterized by a scraper element (L) connected to said gear mechanism so as to rotate with the axis of the paddle in the same or in the opposite direction.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4-6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Earle (US 5,975,751) in view of Foster (WO 01/56514). The relevant teachings of Earle (US 5,975,751) are set forth above. A gear mechanism arranged such that rotation of a handle causes a paddle to rotate about its own axis and also moves the axis of rotation of the paddle is not disclosed. Foster (WO 01/56514) discloses a mixing paddle (3) extending into said mixing chamber and a rotatable handle (5) coupled to said paddle by a gear mechanism (8,10) arranged such that rotation of said handle causes said paddle to rotate about its own axis and also moves the axis of rotation of the paddle within the chamber whereby the paddle is moved around substantially the entire cement containing region of the interior of the chamber. It would have been obvious to one of ordinary skill in the art to have provided the paddle of Earle with a planetary drive as taught by Earle to improve mixing.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Earle (US 5,975,751) in view of Nilson et al (US 5,252,301). The apparatus of Earle was discussed above. The removable fastener is not a pin. Nilson ('301) teaches that a pin is an appropriate removable fastening for retaining a closure in a bone cement mixer (see col. 3, lines 50-68). It would have been obvious to one of ordinary skill in the art to

have utilized a pin as the removably fastener of Earle ('751) based upon the art recognized suitability for this purposed evidenced by Nilson ('301) col. 3, lines 50-68.

11. Claims 11-13 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Earle (US 5,975,751). The apparatus of Earle was discussed above. It is further disclosed that the releasable fastening means provides a friction grip between the closure wall and the inner wall of the chamber (see col. 12, lines 40-67); however, involvement of an O-ring is not explicitly disclosed. Nonetheless, as other portions of the reference (such as col. 12, lines 37-39) recognized that O-rings can be used for sealing and holding in place, utilizing an O-ring would have been obvious to one of ordinary skill in the art.

12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Earle (US 5,975,751) in view of Stump (US 3,450,388). The apparatus of Earle was discussed above. A ball valve is not disclosed. Stump teaches a ball valve (131). It would have been obvious to one of ordinary skill in the art to have provided the apparatus of Earle with a ball valve to control discharge.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID L. SORKIN whose telephone number is (571)272-1148. The examiner can normally be reached on Mon.-Fri. 7:30AM-4:00PM.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID L. SORKIN/  
Primary Examiner, Art Unit 1797